

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Compleat if Known

Application Number

Filing Date

First Named Inventor

William J. Ayala

Art Unit

1610

Examiner Name

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO 00/74655 A2	12-14-2000	Penhasi, et al		
		EP 1 074 249 A1	02-07-2001	Chopinet-Cote, et al		

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NON PATENT LITERATURE DOCUMENTS			
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		AIS, "Job Stress," American Institute of Stress, Paul J. Rosch, M.D., President; 124 Park Avenue, Yonkers, NY 10703	
		ALDRICH, MICHAEL S., M.D.; "Sleep Medicine," Oxford University Press, New York, NY. 1st edition, April 15, 1999; ISBN: 0195129571.	
		BALDESSARINI, R.J.; Drugs and the Treatment of Psychiatric Disorders; in: Gilman AG, Goodman, L.S., Gilman, A., eds, The Pharmacological Basis of Therapeutics. New York: MacMillan Publishing Co Ltd, 1980; 391-447.	
		BEETS, T.A., BIRTLE, J.; Effect of Two Hypnotic Drugs on Actual Driving Performance Next Morning. British Medical Journal 1982; 285:852.	
		BELENKY, G., BALKIN, T. J., et al; "Sustaining Performance During Continuous Operations: the U.S. Army's Sleep Management System," Proceedings of the Army Science Conference, Walter Reed Army Institute of Research, Washington, DC 20307, 1996.	
		BIXLER, E.O.; KALES, A.; SOLDATOS, C.; et al. "Prevalence of Sleep Disorders in the Los Angeles Metropolitan Area." American Journal of Psychiatry, 1979;136:1257-1262.	
		BLS, Current Population Surveys 1994-2003, Monthly Household Data, Tables 46 and 47, Absences from Work of Employed Full-Time Wage and Salary Workers; Bureau of Labor Statistics, U.S. Department of Labor, Postal Square Building, 2 Massachusetts Ave. NE, Washington, DC 20212.	
		BNA, "Focus on Turnover," annual surveys of employee turnover, 1993-2002; Paul N. Wojcik, President and CEO; The Bureau of National Affairs, Inc., 1231 25th St. NW Washington DC 20037.	
		BRACHTEL, D. and RICHTER, E.; Absolute Bioavailability of Caffeine from a Tablet Formulation; Journal of Hepatology, 1992, 16:385.	
		BRODY, JANE E., "When the Eyelids Snap Shut at 65 Miles an Hour;" The New York Times, Science Desk, November 26, 2002	
		BUSTO, U., BENDAYAN, R., SELLERS, E.M.; Clinical Pharmacokinetics of Non-opiate Abused Drugs; Clinical Pharmacokinetics, 1989, 16:1-26.	
		CCH; "Unscheduled Absence Survey," CCH Incorporated, Rebecca Karnes Hensley, President & CEO; 2700 Lake Cook Road, Riverwoods, IL 60015.	
		CARSKADON, M.A.; ROSEKIND, M.R.; et al; "Adolescent Sleepiness During Sleep Restriction in the Natural Environment." J Sleep Research 1989; 18:115.	
		CHENEY, SCOTT; "Keeping Competitive; Hiring, Training, and Retaining Qualified Workers," Center for Workforce Preparation, an affiliate of the U.S. Chamber of Commerce; September 2001	

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		FHWA, "Highway Statistics 2000," Section III: Driver Licensing, Table DL-20: "Distribution of Licensed Drivers 2000, By Sex and Percentage in Each Age Group and Relation to Population", Federal Highway Administration division of the United States Department of Transportation, October, 2001 (updated November 8, 2001).	
		FRISONI, G.B.; DE LEO, D.; ROZZINI, R.; BERNARDINI, M.; et al; "Psychic Correlates of Sleep Symptoms in the Elderly," International Journal of Geriatric Psychiatry, 1992, 7:891-898.	
		GREENBERG, P.E.; STIGLIN, L.E.; FINKELSTEIN, S.N.; BERNDT, E.R.; "The Economic Burden of Depression in 1990;" Journal of Clinical Psychiatry, 1993; 54: 405-418.	
		"Guide to Plastics, The;" a supplement of Modern Plastics, Charles A. Harper, editor, McGraw Hill, New York, 1995.	
		HICKEY, JOHN J. JR., "Shoulder Rumble Strip Effectiveness: Drift-Off-Road Accident Reductions On The Pennsylvania Turnpike," Transportation Research Record 1573 (Paper #970624), TRB, National Research Council, Washington, D.C., 1997, pp. 105-109.	
		HOLMES, T. H. and RAHE, R. H.; "The Social Readjustment Rating Scale;" Journal of Psychosomatic Research, II, p. 216, 1967.	
		HORNE, J. and REYNER, L.; "Sleep Related Vehicle Accidents." British Medical Journal, 1995(b) Mar 4; 310:565-7.	
		Integra Realty Resources, Inc., New York, NY, and Opinion Research Corp. International, Princeton, N.J.; "Desk Rage in America: The Year 2000," November 15, 2000, and Second Annual "Desk Rage in America," 2001, December 13, 2001.	
		JOHNSON, L.C., SPINWEBER, C.L.; "Quality of Sleep and Performance in the Navy: A Longitudinal Study of Good and Poor Sleepers." In: Guilleminault, C., and Lugaresi, E., eds. Sleep/wake Disorders: Natural History, Epidemiology, and Long-term Evolution. New York: Raven Press; 1983:13-28.	
		KARNI, A., TANNE, D., RUBENSTEIN, B.S., ASKENASY, J.J.M., and SAGI, D.; "Dependence on REM Sleep of Overnight Improvement of a Perceptual Skill." Science 1994;265:679-682.	
		KIMKO, H.C., CROSS, J.T., ABERNETHY, D.R.; "Pharmacokinetics and Clinical Effectiveness of Methylphenidate;" Department of Pharmacology, Center for Drug Development Science, Georgetown University Medical Center, Washington, DC 20007, USA, Clinical Pharmacokinetics, 1999 Dec; 37(6):457-70.	
		LADER, M.H., PETURSSON, H.; Benzodiazepine Derivatives – Side-effects and Dangers. Biological Psychiatry 1981; 16:1195-21.	

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		LANGLOIS, P., et al.; "Temporal Patterns of Reported Single Vehicle Car and Truck Accidents in Texas, USA During 1980-83." <i>Chronobiology International</i> , 1985; 2:131-40.	
		LAVIE, P.; "Sleep Habits and Sleep Disturbances in Industrial Workers in Israel: Main Findings and Some Characteristics of Workers Complaining of Excessive Daytime Sleepiness." <i>Sleep</i> , 1981; 4:147-158.	
		LAVIE, P., et al.; "Frequency of Sleep Related Traffic Accidents and Hour of the Day;" <i>Sleep Research</i> 1986; 15:175.	
		LEIGH, J. PAUL; "Employee and Job Attributes and Predictors of Absenteeism in a National Sample of Workers: The Importance of Health and Dangerous Working Conditions." <i>Social Science & Medicine</i> 1991; 33:127-137.	
		LILJENBERG, B.; ALMWVIST, M.; HETTA, J., et al, "Affective Disturbance and Insomnia: a Population Study;" <i>European Journal of Psychiatry</i> ; 1989; 3:91-98.	
		MELLINGER, G.D.; BALTER, M.B.; UHLENHUTH, E.H. "Insomnia and its Treatment: Prevalence and Correlates." <i>Archives of General Psychiatry</i> , 1985;42:225-232.	
		MITLER, M. et al.: "Catastrophes, Sleep, and Public Policy: Consensus Report." <i>Sleep</i> 1988;11(1):100-9.	
		NHTSA, "Traffic Safety Facts 2000 (unabridged)," National Highway Traffic Safety Administration agency of the United States Department of Transportation; December, 2001; DOT HS 809 337.	
		NHTSA, "Traffic Safety Facts 2000: Overview (revised)," National Highway Traffic Safety Administration agency of the U.S. Department of Transportation; Dec., 2001; DOT HS 809 329.	
		NHTSA, "Addressing the Safety Issues Related to Younger and Older Drivers, A Report to Congress," National Highway Traffic Safety Administration agency of the United States Department of Transportation, Office of Program Development and Evaluation, Traffic Safety Programs; January 19, 1993; DOT HS 807 957; NTS-31.	
		NHTSA, KNIPLING, RONALD R. and WANG, J.S.; "Crashes and Fatalities Related to Driver Drowsiness/fatigue;" Research Note from the Office of Crash Avoidance Research, National Highway Traffic Safety Administration agency of the United States Department of Transportation; Washington, DC; 1994 Nov. pp. 1-8.	
		NHTSA, BLINCOE, LAWRENCE J., Plans and Policy office; "The Economic Cost of Motor Vehicle Crashes, 1994;" National Highway Traffic Safety Administration agency of the U.S. Department of Transportation, Washington, DC. NHTSA Technical Report, DOT HS 808 425.	

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		NHTSA, BLINCOE, LAWRENCE J.; SEAY, ANGELA G.' M.Sc.; ZALOSH NJA, EDUARD, Ph.D.; MILLER, TED R., Ph.D.; ROMANO, EDUARDO O., Ph.D.; LUCHTER, STEPHEN; SPICER, REBECCA S., Ph.D.; "Economic Impact of Motor Vehicle Crashes 2000;" National Highway Traffic Safety Administration agency of the United States Department of Transportation; May 2002; DOT HS 809 446.	
		NHTSA, "Mission of Drowsy Driving Program;" Traffic Safety and Occupant Protection section, Injury Prevention, "Drowsy & Distracted Driving;" National Highway Traffic Safety Administration agency of the United States Department of Transportation, http://www.nhtsa.dot.gov/people/injury/drowsy_driving1/index.html .	
		NHTSA, Drowsy Driver Technology Program, Paul S. Rau, Program Manager; National Highway Traffic Safety Administration agency of the United States Department of Transportation, Research and Development Division, NHTSA-NRD-53, updated 10/4/2002.	
		NComSDR, "Wake up America: A National Sleep Alert," Volume 1; Executive Summary and Executive Report, National Commission on Sleep Disorders Research, U.S. Department of Health and Human Services (DHHS), January 1993.	
		NCSDR/NHTSA Expert Panel on Driver Fatigue and Sleepiness, "Drowsy Driving and Automobile Crashes," sponsored by the National Center on Sleep Disorders Research (NCSDR) of the National Heart, Lung, and Blood Institute of the National Institutes of Health, and the National Highway Traffic Safety Administration (NHTSA), 1997.	
		NIMH, "The Invisible Disease: Depression;" National Institute of Mental Health, Thomas R. Insel, M.D., Director, division of the National Institutes of Health (NIH), agency of the U. S. Department of Health and Human Services, 6001 Executive Blvd., Bethesda, MD 20892; NIH Publication No. 01-4591, January, 2001.	
		NMHA, "Depression in The Workplace; National Mental Health Association, Michael M. Faenza, President and CEO; 2001 N. Beauregard Street, 12th Floor, Alexandria, VA 22311; 1996-2003.	
		NSC, "Injury Facts (1999);" The National Safety Council, Alan C. McMillan, President and CEO; 1121 Spring Lake Drive, Itasca, IL 60143	
		NSF, "Sleep in America" Public Opinion Polls, 1995 through 2003; National Sleep Foundation, James K. Walsh, Ph.D., President; 1522 K Street NW, Suite 500, Washington, DC 20005.	
		NSF, "Drowsy Driving, 'The Silent Killer', Facts and Stats," 2002; National Sleep Foundation, James K. Walsh, Ph.D., President; 1522 K Street NW, Suite 500, Washington, DC 20005.	

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		New York State Task Force on the Impact of Fatigue on Driving. "1994 Telephone Survey on Drowsy Driving: Summary Report." Albany, NY; Institute for Traffic Safety Management and Research, December 1994.	
		New York State Task Force on Drowsy Driving, Status report; Institute for Traffic Safety Management and Research; 1996 May.	
		New York State Thruway Authority, Howard E. Steinberg, Chairman; "Thruway Experiences Safest Year Ever"; New York State Thruway Authority NEWS, Feb. 18, 1997.	
		NORRIS, FLOYD; "The Downsizing of America," special series; The New York Times, 229 West 43rd Street, New York, NY 10036, 3/3/96-3/9/96.	
		North Carolina, State of, DOT; Governor's Highway Safety Program, Parker, Joseph, Director; "North Carolina Issues a Wake-Up Call to All Motorists - GHSP Director Urges Drivers Not to Drive While Drowsy," NCDOT GHSP News, March 27, 2000.	
		PACK, A., et al; "Characteristics of Crashes Attributed to the Driver Having Fallen Asleep." Accident Analysis and Prevention, 1995;27(6):769-75.	
		Physicians' Desk Reference (52 Ed. 1998).	
		Romazicon (flumazenil) Injection monograph, revised May 2000, Roche Laboratories Inc., 340 Kingsland Street, Nutley, New Jersey 07110	
		ROTENBERG, V.S., "Sleep and memory I: The influence of different sleep stages on memory." Neuroscience Biobehavior Review 1992;16:497-502.	
		SEITZ, J.A., et al., The Theory and Practice of Industrial Pharmacy, Ch. 12: Tablet Coating. 3rd Ed. Edited by L. Lachman, et al.; Lea and Febiger, Philadelphia, PA, 1986.	
		Shire Pharmaceuticals, "Adderall XR Monograph," (2003 Physicians' Desk Reference) Shire US Inc., Florence, KY 41042	
		SKEGG, D.C.G., RICHARDS, S.M., DOLL, R.; Minor Tranquillisers and Road Accidents. British Medical Journal 1979; 1: 917-19.	
		STOLLER, M.K.; "Economic Effects of Insomnia;" Clinical Therapeutics, 1994;16:263-287 and 873-897.	
		SWANSON, VIVIEN; "Stress: Theories, Causes, and Outcomes;" Anxiety and Stress Research Centre, Department of Psychology, University of Stirling; Stirling, Scotland.	

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		U.S. Department of Health and Human Services; "Mental Health: A Report of the Surgeon General (David Satcher); Chapter 4 - Adults and Mental Health;" U.S. Department of HHS, National Institute of Mental Health, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, subsidiary of The National Institutes of Health; Rockville, MD:1999.	
		WARE, J.C. and MOREWITZ, J.; "Diagnosis and Treatment of Insomnia and Depression." Journal of Clinical Psychiatry 1991;52(Suppl):55-61.	
		WARE, NORMA C., Ph.D., Associate Professor, Departments of Psychiatry and Social Medicine, Harvard Medical School, Boston, Massachusetts 02115, USA.; "Sociosomatics and Illness in Chronic Fatigue Syndrome;" Psychosomatic Medicine; 1998 60: 394-401	
		WELLS, KENNETH B., SCHOENBAUM, MICHAEL, SHERBOURNE, CATHY D., and RUBENSTEIN, LISA; "Brighter Futures - Improvements in Depression Care Pay for Themselves;" RAND Review, Fall 2001 Vol. 25, No. 3; The Rand Corporation, Santa Monica, CA.	
		WESENSTEN, NANCY J., et al; "Executive Health & Fitness; Chap 6 - 'The Role of Sleep in Sustaining Individual & Organizational Effectiveness;'" Army Physical Fitness Research Institute (APFRI), U.S. Army War College, Carlisle Barracks, Pennsylvania 17013	
		WONG, Y.N., SIMCOE, D., HARTMAN, L.N., LAUGHTON, W.B., KING, S.P., MCCORMICK, G.C., GREBOW, P.E.; "A Double-Blind, Placebo-Controlled, Ascending-Dose Evaluation of the Pharmacokinetics and Tolerability of Modafinil Tablets in Healthy Male Volunteers;" Drug Safety and Disposition division of Cephalon, Inc., West Chester, Pennsylvania, USA; Journal of Clinical Pharmacology, 1999 January; 39(1):30-40.	

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